

Atty. Dkt. No. 065678/0101

Naoshi FUKUSHIMA, *et al.*
Serial No. 09/508,251**REMARKS**Status of the Claims

Claims 1-12 have been replaced with claims 13-23. Support for the new claims is found throughout the specification and in the original claims. No new matter has been introduced.

Sequence Listing

A new sequence listing was separately filed today in the PTO mailroom as required by the Office Action.

35 U.S.C. 112

Claims were rejected under the first and second paragraphs of 35 U.S.C. 112 in the Office Action. Reconsideration of the rejections is respectfully requested in view of the foregoing amendments and the following remarks.

Regarding items 4, 6, and 7, the revised claims exclude a peptide and a low molecular weight compound and are limited to a monoclonal antibody or a fragment thereof capable of inducing apoptosis through binding to IAP. Thus, the present claims do not encompass any antibody which cannot bind IAP to induce apoptosis.

The Office Action asserted that the specification does not teach whether the antigen IAP is present on all of the nucleated blood cells. It is now well-known that IAP is specifically expressed on bone marrow cells and derivatives thereof (see, e.g., summary of Reinhold et al.). The myeloid cells and derivatives thereof, i.e. nucleated blood cells, include leukemia cells such as HL-60 cells having IAP. Accordingly, a skilled artisan would know that all nucleated blood cells, including leukemia cells, have IAP on their cell surface.

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The Examiner also asserted that it is unclear whether the claimed monoclonal antibody, fragment thereof or antileukemic agent is capable of inducing apoptosis of cells other than HL-60 or Jurkat cells. However, the specification also discloses the induction of apoptosis of KPMM2 cells. Further, it is also well-known by a person skilled in the art that HL-60 cell, Jurkat cell and KPMM2 are derived from human myeloid leukemia, human T-cell lymphoma and human myeloma cell, respectively, and so are commonly used as a leukemia model. According to the specification, therefore, those skilled in the art should understand that the claimed monoclonal antibody, fragment thereof and antileukemic agent are capable of inducing apoptosis of cells other than HL-60, Jurkat and KMM2 cells.

In any case, this entire argument is irrelevant to present claims 13-19, which claim antibodies that induce apoptosis through binding to IAP on nucleated cells "with" IAP. If there are any nucleated blood cells that lacked IAP, their existence would be irrelevant to the enablement of these claims.

Accordingly, withdrawal of the rejections under 35 U.S.C. 112, first and second paragraphs, are requested.

35 U.S.C. 102(b)

Claims have also been rejected under 35 U.S.C. 102(b) as anticipated by Genestier. Reconsideration of the rejection is respectfully requested.

The Office Action asserted that Genestier discloses an antibody which induces apoptosis in lymphocytes and that IAP is expressed on lymphocytes as evidenced by Reinhold et al. However, the antibody disclosed in Genestier is an antibody against CD40, which plainly differs from the claimed antibody. Furthermore, the present invention first discloses the relationship of IAP (CD47) to apoptosis, and therefore applicants claim an antibody "capable of inducing apoptosis" of the cells "through binding to IAP." There is no reference which teaches or suggests an antibody having this combination of properties. It is quite clear that Genestier's antibody

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binds to a distinct antigen and, to the extent it induces apoptosis at all, it does not do so through binding to IAP as is required by the present claims.

Accordingly, withdrawal of the rejection is respectfully requested.

CONCLUSION

As the above-presented amendments and remarks address and overcome all of the rejections presented by the Examiner, withdrawal of the rejections and allowance of the claims are respectfully requested.

If the Examiner has any questions concerning this application, he or she is requested to contact the undersigned.

Respectfully submitted,

Date

Sept. 18, 2001

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Should additional fees be necessary in connection with the filing of this paper, or if a petition for extension of time is required for timely acceptance of same, the Commissioner is hereby authorized to charge Deposit Account No. 19-0741 for any such fees, and applicant(s) hereby petition for any needed extension of time.